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MEDIA RELEASE

Sandoz launches Pyzchiva® autoinjector, first commercially available in Europe for ustekinumab biosimilars

- Pyzchiva® first ustekinumab biosimilar in Europe commercially available in pre-filled pen (autoinjector), offering improved self-administration experience for better treatment adherence and quality of life [1-10]
- Autoinjector includes unique features to improve comfort, independence and convenience for patients with chronic inflammatory diseases [1-10]
- Launch strengthens Sandoz biosimilar leadership position in immunology and commitment to patient-centric innovation

Basel, May 21, 2025 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, today announced the European launch of its Pyzchiva®* (ustekinumab) autoinjector.[1-2] This is the first ustekinumab biosimilar in Europe commercially available in an autoinjector. Developed and registered by Samsung Bioepis, Pyzchiva® is approved for the treatment of adults with plaque psoriasis, psoriatic arthritis, Crohn's disease and pediatric plaque psoriasis for patients aged six years and older, weighing over 60 kg.[1]

The Pyzchiva® autoinjector supports a more comfortable self-administration experience [1-10] with accurate automatic dosing [1,3,4], less frequent injection pain [1,9,10], a compact design [1,3,4,6,7], and flexible storage options [1], offering the potential for improved adherence to patient treatment plans.

Christophe Delenta, President Europe, Sandoz, said: "Access to medicine does not end when it reaches the hands of the patient. The Pyzchiva® autoinjector, with its thoughtful and advanced features, addresses the real-world needs of patients in managing chronic inflammatory diseases. This launch marks another important milestone as we strengthen our leadership in immunology biosimilars and reaffirm our commitment to pioneering access across Europe's evolving healthcare landscape."

Europe has the highest prevalence of psoriasis worldwide, affecting an estimated 6.4 million people.[11-13] Inflammatory bowel diseases, such as Crohn's disease, are also common in Europe, affecting an estimated 2.5 to 3 million people.[14] Non-adherence to biologic therapies can lead to disease progression, increased flares and reduced quality of life, while contributing to increased healthcare utilization, including hospitalizations and additional treatments, thereby escalating healthcare costs.[15,16]

Pyzchiva® is a key biosimilar value driver for the Sandoz growth strategy. It has been launched in 23 markets in Europe. The autoinjector is now available in Spain and will continue to roll out across Europe.

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Sandoz entered into a development and commercialization agreement for biosimilar ustekinumab with Samsung Bioepis in September 2023. Under the terms of the agreement, Sandoz has the right to commercialize Pyzchiva® in Brazil, the US, the European Economic Area (EEA), Switzerland and the UK. Samsung Bioepis remains responsible for development, registration, intellectual property, manufacturing and supply.

ABOUT PYZCHIVA® (USTEKINUMAB)

Pyzchiva® (ustekinumab) has been developed as a biosimilar with equivalent efficacy and comparable safety to the reference medicine Stelara®**, a human monoclonal antibody against interleukin (IL)-12/23. Pyzchiva® is approved for the treatment of adults with plaque psoriasis, psoriatic arthritis, Crohn's disease and pediatric plaque psoriasis for patients six years and older weighing over 60 kg.

The Pyzchiva® autoinjector is a pre-filled pen delivered through the Molly®*** platform of SHL Medical AG. It is available as a 90 mg in 1 mL autoinjector or a 45 mg in 0.5 mL autoinjector.[1,2]

Pyzchiva® is also available as a 130mg concentrate in a vial for solution for infusion, a 90 mg and a 45 mg concentrate solution for injection in a pre-filled syringe.

*Pyzchiva® is a trademark of Samsung Bioepis Co. Ltd.
**Stelara® is a trademark of Johnson & Johnson
***Pyzchiva® will be delivered by SHL Medical's patented Molly® technology. Molly® is a registered trademark of SHL Medical AG

DISCLAIMER

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly revise any forward-looking statements, except as required by law.

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ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 900 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,300 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2024, Sandoz recorded net sales of USD 10.4 billion.

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